

REMARKS

The specification has been amended to correct informalities in the present application. No new matter has been added in the specification and drawings as originally filed.

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Attached hereto is a marked-up version of the changes made to the specification by the current Preliminary Amendment. The attached page is captioned **“VERSION WITH MARKINGS TO SHOW CHANGES MADE.”**

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please enter the following substitute paragraphs for the specification at page 4, line 3 through line 12:

In a preferred embodiment, the immune globulin source is Cohn's fraction I+II+III or II+III prepared from plasma or plasma intermediates by precipitation of the paste at pH [6.7] 5.7 to [6.8] 5.8 in the presence of 20% ethanol and 80% purified water. As shown in FIG. 1, the immune globulin (or antibody) source, Cohn's fraction I+II+III or II+III, is suspended in a solution consisting of about 19% ethanol and about 81% purified water at a volume equivalent to two times that of the initial source at a temperature in a range of about -4°C to about -6°C with vigorous agitation. It is preferred that the immune globulin suspension is prepared at a temperature of approximately -5°C. Alternative sources of immune globulins or antibodies can be derived from non-human sources such as those from tissue culture or animal origin for use in the present invention.

The precipitation of a majority of phospholipids from the immune globulin suspension is activated by adjusting the pH of the suspension to approximately [6.7] 5.7 to [6.8] 5.8 using 1.0M sodium acetate (or 4.0M sodium acetate for less volume) while continuously agitating the suspension. The suspension is incubated for a minimum of two hours at a temperature in a range of about -4°C to about -6°C with moderate

agitation. Alternatively, liquid-separation of the suspension can be performed at this step in the process, rather than incubation of the suspension, followed by repetition of the earlier steps of preparing the suspension and precipitating the same.

IN THE CLAIMS

Please amend claims 1 and 3 as follows:

1. (Amended) A method for producing a high yield of purified immune globulins from blood plasma, comprising:

providing a plasma source containing immune globulins;

suspending the immune globulins in an ethanol solution at a volume equivalent to two times that of the initial plasma source at a temperature in a range of about -4°C to -6°C;

adjusting the pH of the suspension to about [6.7] 5.7 to [6.8] 5.8;

incubating the suspension for at least two hours;

adding a volume of a solution of about 2.4M glycine in about 7% ethanol and purified water (volume/volume) equivalent to the volume of the plasma source to the suspension;

adjusting the pH of the suspension to about 5.2 to 5.4 with 1.0M to 4.0M sodium acetate;

extracting the immune globulins using liquid-solid separation;

concentrating the protein from the liquid-solid separation by ultrafiltration in a solution of approximately 1.0 gram/deciliter protein content;

performing solvent-exchange on the protein solution with a sodium phosphate solution;

removing any impurities from the protein solution using an anion exchange chromatography column;

concentrating the purified protein deriving from the column effluent by ultrafiltration;

inactivating any viruses present in the concentrated protein solution;

passing the protein solution through a column containing C-18 resin for removal of remaining residue by adsorption, wherein the ratio of protein load volume to resin volume is approximately eight parts load volume to one part C-18 resin; and

formulating the collected protein solution for final use.

3. (Amended) The method of claim 1, wherein the ethanol solution is comprised of about 19% ethanol and about 81% purified water adjusted to a pH of 5.7 to 5.8.

IN THE ABSTRACT

Please enter the following substitute paragraph for the abstract at page 15, line 1 through line 7:

The method for immune serum globulin purification relates to the purification of immune globulins from blood plasma with a high degree of efficiency and a high rate of recovery. The immune globulin source is Cohn's fraction I+II+III or II+III prepared from plasma or plasma intermediates by precipitation of the paste at pH [6.7] 5.7 to [6.8] 5.8 in the presence of 20% ethanol and 80% purified water. A glycine extraction is followed by an anion exchange chromatography column step to achieve a significantly high yield and high purity of the concentrated protein.